

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
FLORENCE DIVISION

Genesis Health Care, Inc.,	)	Civil Action No.: 4:19-cv-1531-RBH
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
Alex M. Azar, II, <i>as Secretary of the United</i>	)	
<i>States Department of Health and Human</i>	)	
<i>Services; George Sigounas, as Administrator</i>	)	
<i>of the Health Resources and Services</i>	)	
<i>Administration; and Krista Pedley, as</i>	)	<b>ORDER</b>
<i>Captain in the United States Public Health</i>	)	
<i>Service and Director of the Office of</i>	)	
<i>Pharmacy Affairs in the Health Resources</i>	)	
<i>and Services Administration,</i>	)	
	)	
Defendants.	)	
	)	

This matter is before the Court for consideration of Defendants Alex M. Azar, II, George Sigounas, and Krista Pedley’s (“Defendants”) motion to dismiss for lack of subject matter jurisdiction, ECF No. 41, and motion to stay discovery, ECF No. 46. For the reasons discussed below, the Court will grant Defendants’ motion to dismiss, thereby rendering Defendants’ motion to stay discovery moot, and dismiss this case without prejudice for lack of subject matter jurisdiction.

**Factual and Procedural History**

Plaintiff is a nonprofit Federally Qualified Health Center (“FQHC”) that provides comprehensive primary and preventative healthcare to patients regardless of their health insurance status and ability to pay. Amended Verified Petition for Judicial Review (“Amended Petition”) ¶ 1. As a FQHC, Plaintiff is eligible to participate in the 340B Program, which is a drug pricing program managed by the Health Resources and Services Administration (HRSA), an agency within Department of Health and Human Services (“HHS”). *Id.* ¶¶ 9-10. The 340B Program allows the HHS Secretary to

enter into agreements with manufacturers of covered outpatient drugs in order to obtain discounts for covered entities, such as Plaintiff, that purchase these drugs for their patients. *Id.* ¶ 10. Plaintiff and other covered entities purchase covered outpatient drugs from manufacturers through wholesalers, and dispense these drugs at wholly-owned and contract pharmacies to individuals who qualify as a covered entity's patients under the 340B Program. *Id.* ¶ 11.

HHS may audit covered entities to evaluate compliance with the statutory requirements of the 340B Program. *Id.* ¶ 13. The Health Resources and Services Administration ("HRSA" or "the agency") is an agency within HHS and is responsible for administering the 340B Program. *Id.* ¶2. Within the HRSA, the Office of Pharmacy Affairs ("OPA") is responsible for conducting audits of covered entities like Plaintiff. *Id.* ¶ 14. In June 2017, OPA conducted a one-and-a-half day on-site audit (the Audit) of Plaintiff. *Id.* On February 14, 2018, OPA issued its Final Report containing its Audit findings. *Id.* ¶ 15. OPA found Plaintiff had "fail[ed] to comply with the statutory eligibility requirement of compliance with auditable records" and therefore, the agency made a preliminary determination that Plaintiff was no longer eligible to participate in the 340B Program and that Plaintiff was liable to manufacturers of covered outpatient drugs for purchases made while it was ineligible for 340B Program participation. *Id.*

On March 13, 2018, Tony R. Megna, Plaintiff's CEO, responded to the agency's Final Audit Report and objected to the Audit's findings. *Id.* ¶ 18. On June 26, 2018, the agency replied to Plaintiff's response and concluded Plaintiff's objections were without merit and Plaintiff was ineligible for participation in the 340B Program. *Id.* ¶ 19. Two days later, on June 28, 2018, Plaintiff filed a verified petition for judicial review and emergency motion to stay before this Court, in which Plaintiff asked this Court to, *inter alia*, impose a temporary stay halting the agency's determination that Plaintiff was

ineligible to participate in the 340B Program and declare Plaintiff eligible under the 340B Program. See ECF No. 1.

On August 23, 2018, this Court entered an Order noting Plaintiff had withdrawn its emergency motion to stay because Plaintiff had been provisionally readmitted to the 340B Program. ECF No. 10. The Court stayed this case at the request of both parties from August 24, 2018 to May 29, 2019 to allow the parties to attempt to resolve this matter without judicial intervention. While this case was stayed, on September 24, 2018, the agency vacated its decision to remove Plaintiff from the 340B Program and promptly reinstated Plaintiff into the 340B Program. Amended Complaint ¶ 22.

Despite HRSA vacating its decision and reinstating Plaintiff into the 340B Program, Plaintiff file a motion to amend its petition, emergency motion to stay, and petition for declaratory relief. *See* ECF No. 33. The Court denied Plaintiff's motion for a preliminary injunction and emergency motion to stay, but granted Plaintiff's motion to amend its petition. ECF No. 44. In the Amended Petition, Plaintiff sought an order from this Court: (1) directing "HRSA to retract any notification it may have provided to manufacturers that Plaintiff is ineligible under the 340B Program"<sup>1</sup>, (2) "set[ting] aside HRSA's determinations pursuant to 5 U.S.C. § 706(2)(A)", and (3) declarative relief "concerning the plain wording of 42 U.S.C. § 256b(a)(5)(B)." ECF No. 33 at 25. After the Amended Petition was filed, on June 6, 2019, OPA voided the audit findings in their entirety, and informed Plaintiff that it "ha[d] no further obligations or responsibilities in regard to the audit, including any actions to submit a

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<sup>1</sup> Although Plaintiff requested this relief in the Amended Petition, this request was made before the agency sent the June 6, 2019 letter informing Plaintiff that, in addition to restoring Plaintiff's eligibility for participation in the 340B Program, the agency was voiding the audit in its entirety. Furthermore, Plaintiff does not address this request for relief in its response to Defendants' motion to dismiss. The contents of the June 2019 letter combined with Plaintiff's silence on this issue in its subsequent filing strongly suggests to this Court that this issue has been resolved since the filing of the Amended Petition. Even assuming *arguendo* this issue has not been fully resolved, it is insufficient to change the Court's conclusion that it does not have jurisdiction over this matter as set forth herein. There is no final agency action to judicially review.

[Corrective Action Plan] or perform the actions outlined in the [Corrective Action Plan] previously submitted to OPA. ECF No. 41, Exhibit A.

Shortly after Plaintiff filed the amended petition, Defendants filed a motion to dismiss for lack of subject matter jurisdiction, ECF No. 41, and a motion to stay discovery, ECF No. 46, pending this Court's ruling on Defendants' motion to dismiss. Plaintiff has responded to both motions. See ECF Nos. 43, 47. Accordingly, both motions are ripe for decision before this Court.

### **Standard of Review**

A Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction raises the fundamental question of whether a court has jurisdiction to adjudicate the matter before it. Fed. R. Civ. P. 12(b)(1). "Federal courts are courts of limited subject matter jurisdiction, and as such there is no presumption that the court has jurisdiction." *Pinkley, Inc. v. City of Frederick, Md.*, 191 F.3d 394, 399 (4th Cir. 1999). In deciding a motion under Rule 12(b)(1), the burden is on the plaintiff to show subject matter jurisdiction exists, and the Court is to "regard the pleadings' as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th cir. 1991) (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982)). "The moving party should prevail only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Id.*

### **Discussion**

Defendants move to dismiss this case in its entirety under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction and mootness. ECF No. 41 at 2. Specifically, Defendants contend (1) this case was rendered moot by the agency's decision to void the audit in its entirety and there is no final

agency action under the APA for Plaintiff to challenge; (2) there is no case or controversy as required by Article III and Plaintiff is now seeking an impermissible advisory opinion; and (3) the Declaratory Judgment Act, 28 U.S.C. § 2201, does not provide an independent basis for this Court to exercise jurisdiction in this case.<sup>2</sup>

Defendants first allege this case should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) because there is no final agency action for Plaintiff to challenge under the APA and therefore, this case is moot. 5 U.S.C. § 702 of the APA provides that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof.” Other than agency action made specifically reviewable by statute, § 704 limits the APA’s non-statutory right of judicial review to final agency action. 5 U.S.C. § 704 (“Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.”)<sup>3</sup>

The Supreme Court has set forth two elements that must be satisfied in order for an agency’s action to be “final” for purposes of judicial review. “First, the action must mark the ‘consummation’ of the agency’s decisionmaking process – it must not be of a merely tentative or interlocutory nature... [a]nd second, the action must be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow’.” *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). “[A]n agency action may be considered ‘final’ only when the action signals the consummation of an agency’s

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<sup>2</sup> Defendants also assert that no constitutional claim lies against the agency or the Defendants in their official capacity because a *Bivens* action cannot lie against either the United States or against federal agents acting in their official capacities. *See Doe v. Chao*, 306 F.3d 170, 184 (4th Cir. 2002). Although the Court recognizes this is a correct statement of the law, the Court does not see its applicability in the instant case because Plaintiff has not asserted a *Bivens* claim. Therefore, the Court will decline to address this reason for dismissal discussed in Defendants’ brief.

<sup>3</sup> As there is no private right of action to enforce agency action related to the administration of the 340B Program, Plaintiff seeks relief on the APA’s general review provisions. 5 U.S.C. §§ 702, 704. *See Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110 (2011).

decisionmaking process *and* gives rise to legal rights or consequences.” *COMSAT Corp. v. National Sci. Found.*, 190 F.3d 269, 274 (4th Cir. 1999). (italics in original).

In this case, the original final agency action was the agency’s determination that Plaintiff was ineligible to continue participating in the 340B Program. It “marked the consummation of the agency’s decisionmaking process” and was one from which “legal consequences will flow.” *Bennett*, 520 U.S. at 178. At the time this action was filed, this was the final agency action Plaintiff sought to challenge in this Court, and this Court had jurisdiction to review the agency’s decision declaring Plaintiff ineligible for participation in the 340B Program. However, after this action was filed, the agency voided the audit in its entirety and reinstated Plaintiff as a covered entity under the 340B Program. As Plaintiff readily admits in its response in opposition to the Defendants’ motion to dismiss, “Defendants [decision to void the audit findings] provides Genesis retroactive relief from the immediate obligations imposed on Genesis by [the agency].” ECF No. 43 at 2. Plaintiff contends they are now “directly challenging the audit process in this action,” but importantly, Plaintiff is not challenging the final result of the agency’s process – the decision to void the audit and restore Plaintiff’s eligibility to participate in the 340B Program. *Id.* at 3.

The difficulty with Plaintiff’s contention is that the “audit process” is not a final agency action susceptible to judicial review under 5 U.S.C. § 704. Plaintiff insists that “absent judicial review, [the agency] will continue to incorporate its unlawful and narrower definition of ‘patient’ into its audit standards so that Genesis, as well as other covered entities, will continue to be subject [to the same standards].” ECF No. 43 at 3. The proper time to challenge this allegedly narrower definition of “patient” is when the definition is used in an audit that marks the completion of the agency’s decisionmaking process and “affect[s] the legal rights of the relevant actors” and has “appreciable legal

consequences.” *Bennett*, 520 U.S. at 178. The agency’s decision to void the audit and restore Plaintiff’s status as a covered entity in the 340B Program plainly fails to affect Plaintiff’s legal rights - in fact, it restores Plaintiff’s rights exactly as they were before the audit occurred. Therefore, the agency’s decision to void the audit produced no “appreciable legal consequences” and is not a final agency action subject to review under the APA. See *id.* (discussing *Dalton v. Specter*, 511 U.S. 462 (1994); and *Franklin v. Massachusetts*, 505 U.S. 788 (1992)).

Defendants next allege that, because there is no final agency action, there is no case or controversy as required by Article III and Plaintiff is now seeking an impermissible advisory opinion on the definition of the word “patient” in the event of a future audit. ECF No. 41 at 8. In a separate but related argument, Defendants contend the Declaratory Judgment Act does not provide an independent basis for this Court to exercise jurisdiction over this case. Plaintiff argues it “face[s] an ongoing and imminent threat of auditing and enforcement based on the Defendants’ [alleged unlawful] auditing standards” and therefore this matter is still properly before the Court.

Because these issues involve intertwined doctrines of justiciability, the Court finds it necessary to begin with an overview of these doctrines. Article III of the United States Constitution limits the jurisdiction of federal courts to deciding “cases” and “controversies.” U.S. Const. Art. III, § 2. “It has long been settled that a federal court has no authority ‘to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in issue in the case before it.’”<sup>4</sup> *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quoting *Mills v.*

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<sup>4</sup> The case-or-controversy requirement applies equally in actions seeking declaratory relief, such as the case at bar. See *Golden v. Zwickler*, 394 U.S. 103, 108 (1969). To satisfy the case-or-controversy requirement in an action seeking declaratory relief, “the facts alleged, under all circumstances, [must] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

*Green*, 159 U.S. 651, 653 (1895)).

An actual controversy must exist at all stages of federal court proceedings. If events subsequent to the filing of the case resolve the dispute, the case should be dismissed as moot. *Pashby v. Delia*, 709 F.3d 307, 316 (4th Cir. 2013). “[M]ootness is the doctrine of standing in a time frame...[t]he requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” *United States Parole Comm’n v. Geraghty*, 445 U.S. 388, 397 (1980), quoting Henry Monaghan, *Constitutional Adjudication: The Who and When*, 82 Yale L.J. 1363, 1384 (1973). “Federal courts lack jurisdiction to decide moot cases because their constitutional authority extends only to actual cases or controversies.” *Iron Arrow Honor Soc. v. Heckler*, 464 U.S. 67, 71 (1983). “A case is moot when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome.” *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 287 (2000) (citation and internal quotations omitted); *Williams v. Ozmint*, 716 F.3d 801, 809 (4th Cir. 2013) (citation omitted).

A federal court has subject matter jurisdiction over a claim for declaratory relief if “(1) the complaint alleges an actual controversy between the parties of sufficient immediacy and reality to warrant the issuance of a declaratory judgment; (2) the court possesses an independent basis for jurisdiction over the parties (e.g., federal question or diversity jurisdiction); and (3) the court does not abuse its discretion in its exercise of jurisdiction.” *Volvo Constr. Equip. N. Am. Inc. v. CLM Equip. Co.*, 386 F.3d 581, 592 (4th Cir. 2004). “[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites.” *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995).

The Court begins with the first jurisdictional prerequisite, which is often called the “Constitutional inquiry” because a case “meets the actual controversy requirement [for declaratory



relief] only if it presents a controversy that qualifies as an actual controversy under Article III of the Constitution.” *Volvo Constr. Equip. N. Am. Inc.*, 386 F.3d at 592. An actual controversy is one that is “definite and concrete, touching the legal relations of parties having adverse legal interests,” “real and substantial,” and one that seeks “specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)).

In the case at bar, the parties ceased to have a “definite and concrete” controversy when the agency decided to void its audit findings. The specific relief Plaintiff originally requested, to be restored as a “covered entity” in the 340B Program, has already been provided by the agency. At this time, the relief requested in Plaintiff’s amended petition seeks to have this Court render exactly the type of impermissible advisory opinion contemplated by the Supreme Court in *MedImmune*. Because the case-or-controversy requirement is not satisfied in this case, this case is moot. *See Simmons*, 634 F.3d at 763.

There is, however, a well-recognized exception to the mootness doctrine for conduct “capable of repetition, yet evading review.” *Fed. Election Comm’n v. Wisc. Right to Life, Inc.*, 551 U.S. 449, 462 (2007). This exception applies when “(1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again.” *Id.*

Although Plaintiff does not cite any applicable case law or expound upon this argument in great detail, Plaintiff alludes to this doctrine several times in its response to Defendants’ motion to dismiss. Plaintiff stated “Defendants’ internal policies and procedures that formed the basis of the voided audit

are unlawful and clearly capable of repetition as to Genesis and/or any other ‘covered entity’ that [the agency] audits under its statutory authority.” ECF No. 43 at 2. While Plaintiff contests the Defendants’ allegedly narrower definition of the word “patient,” Plaintiff does not otherwise specify what internal policies or procedures are unlawful, nor does Plaintiff explain how a future decision from the agency would “evade review.” The present case is not one which was “too short,” rather, as Plaintiff admits in its brief, it is a case in which the initial challenged agency action was voided in its entirety. Plaintiff asserts “Defendants’ unlawful and narrowed definition of ‘patient’ is still firmly incorporated into Defendants’ audit standards,” but there is no audit upon which Plaintiff can make such an allegation. ECF No. 43 at 2. Without an active audit that would allow this Court to review the agency’s allegedly unlawful definition of “patient,” this case is moot and the “capable of repetition, yet evading review” exception is inapplicable.

### **Conclusion**

For the foregoing reasons, the Court **GRANTS** Defendants’ motion to dismiss. Accordingly, Defendants’ motion to stay discovery, ECF No. 46, is **MOOT**. Therefore, this case is **DISMISSED WITHOUT PREJUDICE** for lack of subject matter jurisdiction.

**IT IS SO ORDERED.**

Florence, South Carolina  
December 18, 2019

s/ R. Bryan Harwell  
R. Bryan Harwell  
Chief United States District Judge